

**RESPONSE UNDER 37 C.F.R. § 1.116**  
**U.S. Application No. 10/532,605 (Q87625)**

**REMARKS**

**Status of Claims**

Claims 6, 9-11 and 17-42 are all the claims pending in the application.

**Response to Rejection Under 35 U.S.C. § 103(a)**

Claims 6, 9-11 and 17-42<sup>1</sup> were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shih *et al.* in view of Olsen *et al.* and further in view of Genov *et al.* (Biochem J., 207:193-200 (1982)).

Shih and Olsen were relied upon in the Office Action for the reasons already of record. For brevity, those reasons are not reiterated herein.

In addition, the Office Action asserted that Applicants' arguments that the claimed enzyme and subtilisin DY do not possess the same identical chemical structure is not persuasive because of the alleged contradictory disclosure at page 33, 2<sup>nd</sup> paragraph of Applicants' specification that the amino acid sequence of the purified enzyme in Example 1 is identical to subtilisin DY. The Office Action also asserted that the specification at page 29, 3<sup>rd</sup> paragraph discloses an enzyme having a molecular weight close to the molecular weight taught by Olsen.

Genov appears to be asserted by the Office Action for teaching subtilisin DY derived from *Bacillus* that is a serine protease with an optimum pH of about 10 for proteolytic activity. Thus, the Office Action asserts that it would have been obvious for one of ordinary skill in the art at the time the invention was made, to substitute one known enzyme with another, and that such substitution would have yielded predictable results.

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<sup>1</sup> Although the Office Action at page 4 stated that “[c]laims 6, and 17-30 are rejected under 35 U.S.C. § 103(a)”, it appears to Applicants the Office also intended to reject claims 9-11 and 31-42, since these claims were referred to at page 5 of the Office Action and all claims were rejected on the face of the PTOL-326 form.

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Initially, Applicants note that it appears from the Office Action's withdrawal of the earlier §103(a) rejection based only on Shih and Olsen, that the Office Action has admitted that these are deficient references, and that, even combined, they do not teach or suggest the claimed invention. Accordingly, the Examiner appears to be reasserting these two references in the present Office Action because of an impression that the addition of Genov would cure the deficiencies of Shih and Olsen. However, as discussed below, even with the addition of Genov, the Examiner has again failed to establish a *prima facie* case of obviousness.

First, neither Shih, Olsen, or Genov teach or suggest each and every limitation of the presently claimed invention. *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974). As admitted on page 6, lines 9-13 of the present Office Action and as previously argued, Shih does not disclose the presently claimed enzyme possessing the claimed properties. Further, as previously argued, Olsen does not disclose the presently claimed enzyme because Olsen discloses a subtilisin DY having a molecular weight of 27 kDa (see Table 2 of Olsen). Genov does not cure the deficiencies of Shih and Olsen, because Genov similarly discloses a subtilisin DY from *Bacillus subtilis* having a molecular weight of 27.7 kDa (see page 195, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph under "Results" of Genov). Also, contrary to the Office Action's assertions, there is nothing in Genov that teaches or suggests that the disclosed subtilisin DY of Genov has an optimum pH of about 10 for proteolytic activity.<sup>2</sup> Accordingly, because the molecular weight of the claimed enzyme is different from the molecular weights of the enzymes described in Shih, Olsen and Genov, the claimed enzyme is compositionally different from the enzyme described in Shih, Olsen and

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<sup>2</sup> In particular, there is no disclosure provided at "Genov et al. Introduction 1<sup>st</sup> column last paragraph and 2<sup>nd</sup> column 1<sup>st</sup> paragraph" (see page 7 of the Office Action), that the enzyme described in Genov has an optimum pH of about 10 for proteolytic activity.

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Genov. The Examiner is respectfully reminded that the molecular weight is commonly known in the chemical art to account for the isotopic *composition* of a molecule. In the present case, because the claimed enzyme has a different molecular weight than the enzyme disclosed in Shih, Olsen, or Genov, this means that the composition of the claimed enzyme is *different* from the composition of the enzymes disclosed by Shih, Olsen, or Genov. Thus, none of the cited references teach or suggest each and every limitation of the claimed enzyme or method of using the claimed enzyme.

Second, the Examiner has failed to provide reasons why one of skill in the art would combine the cited references to arrive at the claimed invention. M.P.E.P. § 2143.01. As previously argued, while the claimed enzyme and subtilisin DY may share the same amino acid sequence, they do not possess the same chemical structure.<sup>3</sup> For instance, as discussed above, the chemical difference is evidenced by the difference in molecular weights between the claimed enzyme (31kDa), and the subtilisin DY described in Olsen (27kDa) and Genov (27.7 kDa). Accordingly, the Office's assertions that the specification at page 29, 3<sup>rd</sup> paragraph discloses an enzyme having a molecular weight close to the molecular weight taught by Olsen provides no further technically reasonable grounds to show why one of ordinary skill in the art would have the desire to combine Olsen and Genov with Shih in order to substitute the protein of Shih with the protein of Olsen and/or Genov.

For that matter, even if one of ordinary skill in the art was somehow motivated to make such a combination, for the reasons discussed above and previously argued, namely, that the

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<sup>3</sup> Such arguments are not contradictory with Applicants' disclosure at page 33, 2<sup>nd</sup> paragraph that the amino acid sequence of the purified enzyme in Example 1 is identical to subtilisin DY.

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enzymes disclosed in the cited references are chemically different from the claimed enzyme, the combination would not result in the claimed enzyme of the present invention.

Reconsideration and withdrawal of the rejection under § 103(a) is respectfully requested.

**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby earnestly solicited.

If any points remain in issue which the Office feels may be best resolved through a personal or telephone interview, the Office is kindly requested to contact the undersigned at the telephone number listed below.

The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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